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(54) Title: AN IRRIGATING MEDIUM FOR ROOT CANALS

(57) Abstract

The use of antiseptics in root canal treatment so as to reduce the proliferation of bacteria and other microorganisms remaining i n the root canal after obturation.

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TITLE:

AN IRRIGATING MEDIUM FOR ROOT CANALS

INTRODUCTION AND BACKGROUND TO THE INVENTION

This invention relates to the use of antiseptics in root canal treatment so as to reduce the proliferation of bacteria and other micro-organisms remaining in the root canal after obturation.

Sodium hypochlorite is universally used as an antiseptic for root canal irrigation, its principal functions in root canal treatment being microbicidal, dissolving organic material and lubrication. However, a disadvantage of sodium hypochlorite is that it is highly toxic to human tissues and cells in concentrated form and potentially even fatal at the concentrations at which it is at its most effective as an irrigating medium.

OBJECT OF THE INVENTION

It is accordingly an object of this invention to provide a novel, relatively inexpensive and safe irrigating medium for root canals.

SUMMARY OF THE INVENTION

According to a first aspect of the invention there is provided the use of an aqueous solution in the preparation of an irrigating medium for use in the treatment of root canals, the aqueous solution being characterised in that it is electro-chemically activated. The electro-chemically activated aqueous solution may consist of an aqueous anion-containing and/or an aqueous

cation-containing solution. The aqueous anion-containing solution and/or aqueous cation-containing solution may be prepared by means of electrolysis of an aqueous solution of a salt. The salt may be sodium chloride. In particular, it may be non-iodated sodium chloride or potassium chloride.

The anion-containing and the associated cation-containing solution may be produced by an electro-chemical reactor or so-called electrolysis machine. The anion-containing solution is referred to hereinafter for brevity as the "anolyte solution" and the cation-containing solution is referred to hereinafter for brevity as the "catholyte solution". The anolyte solution and the catholyte solution are preferably provided from an electro-chemical reactor comprising a through-flow, electro-chemical cell having two co-axial electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into cathodic and anodic chambers.

The anolyte solution may be produced from a 10% aqueous NaCl solution, electrolysed in the anodic chamber to produce activated or excited aqueous solutions containing numerous free radicals, the anolyte solution having an extremely high redox potential of up to about +1170 mV and a pH value of about 2-7. These activated radical species may be labile and after about 96 hours the various radical species may disappear with no residues being

produced.

The anolyte solution may include activated radical species such as ClO; ClO^-; HClO; OH^-; HO_2^-; H_2O_2; O_3; $HO^\cdot$; $S_2O_8^{2-}$ and $Cl_2O_6^{2-}$.

The activated radical species have been found to have a synergistic anti-bacterial and/or anti-viral effect which is generally stronger than that of chemical bactericides and has been found to be particularly effective against viral organisms, spore and cyst forming bacteria including Gram positive and Gram negative bacteria such as *Enterococcus faecalis* and *Pseudomonas aeruginosa*.

The catholyte solution generally may have a pH of up to about 7-13 and a redox potential of about -980 mV. The catholyte solution may include activated radical species such as NaOH; KOH; $Ca(OH)_2$; $Mg(OH)_2$; $HO^\cdot$; $H_3O_2^\cdot$; HO_2^-; $H_2O_2^-$; O_2^-; OH^-; O_2^{2-}.

It is believed that the activated oxidising radical species or free radicals present in the anolyte solution act synergistically as a biocidal and virucidal agent at a bacterial cellular level, while the activated reducing radical species or free radicals present in the catholyte solution act synergistically as a cleaning agent to dissolve organic material or biofilm protecting or

covering micro-organisms and with the micro-organisms themselves.

It has been found that the efficacy of the use of the anolyte and/or catholyte solution in the preparation of an irrigating medium for use in the treatment of root canals depends upon the concentration of the anolyte and/or the catholyte solutions, as measured by the oxidation-reduction potential (ORP) or redox potential of the anolyte and/or the catholyte solution, the exposure time, i.e. the contact time between the root canal and the anolyte and/or the catholyte solutions and the temperature during application. Anolyte has been found to be more effective at lower than at higher temperatures.

According to a second aspect of the invention there is provided an irrigating medium for irrigating root canals, the irrigating medium comprising an aqueous solution being substantially as hereinbefore defined.

According to a third aspect of the invention there is provided a method for irrigating root canals including the step of applying an electro-chemically activated aqueous solution to a root canal, substantially as hereinbefore defined.

DETAILED DESCRIPTION OF THE INVENTION

The method of irrigating root canals may include the steps of first applying catholyte solution to the root canal, aimed at removing organic biofilm and debris covering the inner walls of the root canal, and thereafter applying anolyte solution to the root canal, aimed at disinfecting the inner walls of the root canal and inner tubes in a tooth.

A preferred embodiment of the invention will now be described by means of two non-limiting examples.

1. **Example No. 1**

20 single rooted teeth were collected from the Department of Oral and Maxillofacial Surgery of the Faculty of Dentistry of the University of Pretoria, South Africa, immediately after extraction from patients' mouths.

1.1 **Testwork**

The extracted teeth were rinsed under running potable water and stored in specimen bottles filled with distilled water for 24 hours. The pulp chambers of the teeth were then accessed by the use of fissure burs in turbine handpieces and round burs in contra-angle handpieces.

A number 15 K-type root canal file was then introduced into each root canal to establish the patency of the canal. The exact length of each canal was determined by inserting a file into the root canal until its tip just appeared through the apical foramen. A silicone rubber stop pre-fitted to the shaft of the file was then adjusted to a coronal reference point, an intact part of the tooth.

The file was then withdrawn and the length from file tip to silicone stop was noted. An individual working length for each tooth was calculated by subtracting 1 mm from the measured length. The coronal thirds of all canals were pre-flared using Gates Glidden burs in a contra-angle handpiece. At this stage, the 20 teeth were randomly divided into two groups, namely Group A and Group B, for irrigation with the conventional sodium hypochlorite and the electro-chemically activated solution (STEDS) in accordance with the present invention respectively, each group consisting of 10 teeth.

Group A (sodium hypochlorite) :

The root canals of Group A were prepared, using a series of K-type files (size 15-60) manually and by irrigating with a 2,5% solution of sodium hypochlorite, with an ultrasonic unit such as a so-called Cavi-Endo (Dentsply) unit. Irrigation was performed after the use of every size file for at least 10 seconds, using the same ultrasonic unit.

After the canal was prepared to a size 60, a final flush of irrigation was carried out for a minimum of 30 seconds. A minimum of 150 ml of 2,5% sodium hypochlorite was used in the irrigating process of each tooth.

Group B (Electro-chemically Activated Solution "STEDS")

STEDS was produced from a specially manufactured electro-chemical reactor, comprising a through flow, electro-chemical cell having two co-axial cylindrical electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into cathodic and anodic chambers. The STEDS produced included two separate solutions, namely catholyte and anolyte solutions. The anolyte solution had a pH of about 7.4 and a redox potential of about + 1170 mV. The

catholyte solution had a pH of about 9,5 and a redox potential of about -980mV. These solutions were used to irrigate the canals in Group B. Root canals were prepared using the same size and types of files and the same manual techniques as in Group A. Initially the catholyte solution was used to irrigate the canals using the same ultrasonic unit as group B. After the use of each size file, the canal was irrigated with anolyte solution for at least 10 seconds.

After preparation to a size 60, a final flush of irrigation was carried out for a maximum of 30 seconds using catholyte solution. A minimum of 100 ml anolyte and 50 ml catholyte solutions were used for each tooth.

Immediately after the above preparation and irrigation procedures had been carried out, the teeth were again stored in distilled water for 24 hours. Each tooth was then dissected with the aid of a microtome. Specimens of the root canal walls of the middle third of the roots, measuring roughly 2 mm by 2 mm, were prepared. The specimens were handled with locking forceps throughout, eliminating contamination by human hand. The specimens were placed into a dust-free

incubator and allowed to air-dry for 10 days.

The air-dried specimens were mounted with conductive adhesive onto metal bases and coated with gold and viewed in a scanning electron microscope at various magnifications. The amount of remaining debris on the root canal walls were compared by noting the debris on the surfaces of twenty representative samples of each group.

1.2 **Results**

The remaining debris in Group B was negligible. Group A exhibited small but noticeable amounts of debris on the surface of a number of specimens. In group B, it was noticed that the so-called smear layer, clearly present in all samples of Group A, had been removed in large areas.

Under the conditions of this study, STEDS compared favourably as an irrigating material with sodium hypochlorite. It removed a large degree of debris from the surfaces of the prepared root canal walls.

2. Example 2

2.1 Testwork

69 extracted teeth, had their root canals prepared in the same manner as in Example 1. The teeth were then sterilised by means of an autoclave and were placed under aseptic conditions in 200 ml of BHI (brain-heart infusion) liquid culture medium together with 1.0 ml of an overnight broth culture of each of the following organisms: *E.faecalis, P.aeruginosa* and *S.mutans*. The teeth were kept in this broth for 7 days in an incubator at 37° C.

At the end of the 7 day period, the teeth were removed with a pair of sterile forceps from the broth. The bioload was expected to be extremely high by this time and colony counts were performed on the broth by doing a series of 10-fold dilutions in triplicate. Aliquots of these dilutions (100 µl) were spotted on 10% blood agar plates and spread with a sterile metal spreader over the surface of the plates. After overnight incubation at 37°C, these plates were counted and the number of colony-forming units (cfus) estimated.

The teeth were washed together in a sterile bottle with 100 ml

of normal saline, repeated 4 times, with fresh saline being added after the contaminated saline was discarded. This reduced the bioburden to a level where the technologist carrying out the procedure was unlikely to develop an infection from spray aerosols.

The teeth were placed with the access cavity side facing upwards in sterile micro titre trays. Prior to treatment, all the teeth were "irrigated" down the access cavity with 50 ml sterile water using a syringe, for 5 minutes, this being similar to a manual irrigation procedure in the dental surgery. The teeth were then held upside-down for a few seconds to allow most of the water to drain off. The teeth were then divided into different groups for the various treatments.

Three groups of 20 teeth each were created, with three individual teeth serving as the catholyte control group and the six other teeth for whole tooth studies.

In Group A (negative control) all the teeth's root canals were irrigated with saline for 5 minutes, using a fine-needle tuberculin syringe. 30 µl saline was then aspirated from the

root canals, serially diluted and spread plated onto 10% blood agar plates and incubated at 37°C for 24 hours.

In Group B, 20 teeth were similarly treated with sodium hypoclorite for 5 and 10 minutes respectively. After 5 minutes and again after 10 minutes, the canals were filled with saline, and 30µl saline were then aspirated, diluted, plated, and incubated.

In Group C all teeth were first treated with catholyte for 5 minutes. After this time, the catholyte was rinsed off with anolyte solution. The teeth were then treated with anolyte for 5 and 10 minutes respectively. At the end of these periods, the same culturing procedure, using saline, was used to take samples from the root canals.

Whole tooth studies were conducted on six of the teeth, as mentioned above. Two of the teeth were stored in sodium hypochlorite and cultures taken after 5 and 10 minutes. The two remaining teeth were stored in the catholyte, rinsed with – and stored in the anolyte. Cultures were taken after 5 and 10 minutes storage time.

2.2 Results

2.2.1 Baseline counts

The broth was shown to contain 4.4×10^{10} cfus after 7 days' incubation with frequent additions of fresh culture medium. The average numbers of organisms present in the root canals after treatment with saline only was 1.4×10^{6} cfus. The reason for this high count was that most of the organisms remained behind as a biofilm. An unexpected finding was that following catholyte treatment (with no anolyte), the count went up to 2×10^{7} cfus. This is presumably because catholyte is known to act in a similar way to a detergent, lifting the biofilm from the surface.

2.2.2 **Test Products**

AVERAGE NUMBER OF COLONY-FORMING UNITS IN ROOT CANALS OBTAINED AFTER EXPOSURE

	SODIUM HYPOCHLORITE	ANOLYTE
5 minutes exposure	0	400
10 minutes exposure	0	0

2.2.3 **Whole Tooth Counts**

When the teeth were treated with sodium hypochlorite only for 5 minutes, the average count was 4×10^2 cfus. The counts dropped to zero when left for 10 minutes.

Using anolyte only (no catholyte pre-treatment) the average count was 1.2×10^5. However, when the teeth were exposed to catholyte, irrigated and then treated with anolyte for 10 minutes, the count dropped to zero.

This in vitro study shows that anolyte is highly effective in

eradicating both planktonic and sessile organisms adherent to the tooth surface.

It is important that catholyte be applied first and then the catholyte and the loosened biofilm MUST be rinsed off for really effective results with the anolyte treatment.

It will be appreciated that many variations in detail are possible without departing from the scope and/or spirit of the invention as defined in the claims hereinafter.

CLAIMS

1. Use of an aqueous solution in the preparation of an irrigating medium for use in the treatment of root canals, the aqueous solution being characterised in that it is electro-chemically activated.

2. The use as claimed in claim 1, wherein the electro-chemically activated aqueous solution includes an aqueous anion-containing and an aqueous cation-containing solution.

3. The use as claimed in claim 2, wherein the aqueous anion-containing solution and the aqueous cation-containing solution are prepared by means of electrolysis of an aqueous solution of a salt.

4. The use as claimed in any one of the preceding claims wherein the anion-containing and the cation-containing solution are produced by an electro-chemical reactor comprising a through-flow, electro-chemical cell having two co-axial electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into cathodic and anodic chambers.

5. The use as claimed in any one of the preceding claims wherein the

anion-containing solution is produced from a 10% aqueous NaCl solution, electrolysed to produce activated or excited radical cation and radical anion species, the anion-containing solution having an extremely high redox potential of up to about +1170 mV.

6. The use as claimed in claim 5 wherein the anion-containing solution has a pH of about 2-7 and a redox potential of about +1170 mV.

7. The use as claimed in claim 5 wherein the cation-containing solution has a pH of up to about 7-13 and a redox potential of about -980 mV.

8. An irrigating medium for irrigating root canals, the irrigating medium comprising an electro-chemically activated, aqueous saline solution.

9. A method for irrigating root canals including the step of applying an electro-chemically activated, aqueous saline solution to a root canal for irrigation purposes.

10. The method as claimed in claim 9 including the steps of first applying cation-containing solution to the root canal, aimed at removing organic film and debris covering the inner walls of the root canal, and thereafter applying an anion-containing solution to the root canal, aimed at disinfecting the inner walls of the root canal and dentinal tubules.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/27380

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 5-7
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/27380

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :H05F 3/00; A61C 5/04
US CL :204/164; 433/226
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 204/164; 433/226

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y ---- X	Database WPIDS, London: Derwent Publications Ltd., AN 96-105648, WO 9602271 A1, (MEDI-N) MEDICAL DISCOVERIES INC, "Microbicidal soln. contg. ozone and active chlorine species - prepd. by electrolysis of saline, for in vitro decomtamination of blood etc. or for in vivo treatment of infection, esp. HIV or hepatitis.", abstract, 01 February 1996, Vol 11, see the entire abstract.	1-4, 9 ---- 8

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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Date of the actual completion of the international search
26 APRIL 1999

Date of mailing of the international search report
14 MAY 1999

Name and mailing address of the ISA/US
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Authorized officer
FREDERICK KRASS
Telephone No. (703) 308-1235

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PATENT COOPERATION TREATY

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From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

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Nath & Associates
6th floor
1030 15th Street, N.W.
Washington, DC 20005
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 14 August 2000 (14.08.00)	
Applicant's or agent's file reference 23800 PCT	**IMPORTANT NOTIFICATION**
International application No. PCT/US98/27380	International filing date (day/month/year) 24 December 1998 (24.12.98)
International publication date (day/month/year) 08 July 1999 (08.07.99)	Priority date (day/month/year) 30 December 1997 (30.12.97)
Applicant RADICAL WATERS IP (PTY) LTD. et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.

3. An **asterisk(*)** appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

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Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
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PCT/US98/27380

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NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

From the INTERNATIONAL BUREAU

To:
NATH, Gary, M.
Nath & Associates
6th floor
1030 15th Street, N.W.
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ÉTATS-UNIS D'AMÉRIQUE

Date of mailing (day/month/year) 08 July 1999 (08.07.99)	
Applicant's or agent's file reference 23800 PCT	**IMPORTANT NOTICE**
International application No. PCT/US98/27380	**International filing date** (day/month/year) 24 December 1998 (24.12.98)
	Priority date (day/month/year) 30 December 1997 (30.12.97)
Applicant RADICAL WATERS (PROPRIETARY) LIMITED et al	

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
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   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
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   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
   08 July 1999 (08.07.99) under No. WO 99/34652

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, **a demand for international preliminary examination** must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the **national phase**, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer J. Zahra
Facsimile No. (41-22) 740.14.35	Telephone No. (41-22) 338.83.38

Form PCT/IB/308 (July 1996)

2710606

P. ENT COOPERATION TREA

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 20 August 1999 (20.08.99)	
International application No. PCT/US98/27380	**Applicant's or agent's file reference** 23800 PCT
International filing date (day/month/year) 24 December 1998 (24.12.98)	**Priority date** (day/month/year) 30 December 1997 (30.12.97)
Applicant MARAIS, Jacobus, Theodorus	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

15 July 1999 (15.07.99)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer R. Forax
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 23800 PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US98/27380	International filing date *(day/month/year)* 24 DECEMBER 1998	Priority date *(day/month/year)* 30 JANUARY 1997
International Patent Classification (IPC) or national classification and IPC IPC(7): H05F 3/00; A61C 5/04 and US Cl.: 204/164; 433/226		
Applicant RADICAL WATERS (PROPRIETARY) LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15 JULY 1999	05 APRIL 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer FREDERICK KRASS Telephone No. (703) 308-2351

JOYCE BRIDGERS
PARALEGAL SPECIALIST
CHEMICAL MATRIX

Form PCT/IPEA/409 (cover sheet) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US98/27380

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-15 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the claims:
pages 16-18 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the drawings:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [X] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US98/27380

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 5-7

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination *(specify)*.

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 5-7 are so unclear that no meaningful opinion could be formed *(specify)*.

Claims 5-7 will not be examined because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 5-7 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US98/27380

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	1-4, 8-10	YES
	Claims	NONE	NO
Inventive Step (IS)	Claims	1-4, 8-10	YES
	Claims	NONE	NO
Industrial Applicability (IA)	Claims	1-4, 8-10	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 1-4 and 8-10 meet the criteria set out in PCT Article 33(2)-(3), because the prior art of record does not fairly teach or suggest electrochemically activated irrigating media for use in treating root canals, nor methods for treating root canals.

Claims 1-4 and 8-10 meet the criteria set forth in PCT Article 33(4); the applicability of the claimed methods and compositions to the dental industry is self-evident.

---------- NEW CITATIONS ----------

NONE

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

I. BASIS OF REPORT:

5. (Some) amendments are considered to go beyond the disclosure as filed:
NONE

16

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 23800 PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US98/27380	International filing date *(day/month/year)* 24 DECEMBER 1998	Priority date *(day/month/year)* 30 JANUARY 1997
International Patent Classification (IPC) or national classification and IPC IPC(7): H05F 3/00; A61C 5/04 and US Cl.: 204/164; 433/226		
Applicant ~~RADICAL WATERS (PROPRIETARY) LIMITED~~ RADICAL WATERS IP (PTY) LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15 JULY 1999	05 APRIL 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer FREDERICK KRASS JOYCE BRIDGERS PARALEGAL SPECIALIST CHEMICAL MATRIX Telephone No. (703) 308-2351

Form PCT/IPEA/409 (cover sheet) (July 1998)★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US98/27380

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-15, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the claims:
pages 16-18, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the drawings:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [X] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US98/27380

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 5-7

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination *(specify)*.

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 5-7 are so unclear that no meaningful opinion could be formed *(specify)*.

Claims 5-7 will not be examined because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 5-7 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US98/27380

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	1-4, 8-10	YES
	Claims	NONE	NO
Inventive Step (IS)	Claims	1-4, 8-10	YES
	Claims	NONE	NO
Industrial Applicability (IA)	Claims	1-4, 8-10	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 1-4 and 8-10 meet the criteria set out in PCT Article 33(2)-(3), because the prior art of record does not fairly teach or suggest electrochemically activated irrigating media for use in treating root canals, nor methods for treating root canals.

Claims 1-4 and 8-10 meet the criteria set forth in PCT Article 33(4); the applicability of the claimed methods and compositions to the dental industry is self-evident.

---------- NEW CITATIONS ----------

NONE

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

I. BASIS OF REPORT:

5. (Some) amendments are considered to go beyond the disclosure as filed:
NONE

GMN HN 1

PATENT COOPERATION TREATY

4/25/00 ORJ

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: GARY M. NATH
NATH & ASSOCIATES
1030 15TH STREET, N.W.
6TH FLOOR
WASHINGTON, DC 20005

RECEIVED
APR 20 2000

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing *(day/month/year)*	19 APR 2000

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
23800 PCT	

International application No.	International filing date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/US98/27380	24 DECEMBER 1998	30 JANUARY 1997

Applicant
RADICAL WATERS (PROPRIETARY) LIMITED

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	FREDERICK KRASS
Facsimile No. (703) 305-3230	Telephone No. (703) 308-2351

JOYCE BRIDGERS
PARALEGAL SPECIALIST
CHEMICAL MATRIX

Form PCT/IPEA/416 (July 1992)★

FILING RECEIPT

Attorney Docket No. 23800-PCT

In re Application of:

RADICAL WATERS (PROPRIETARY) LIMITED et al.

Application No.: PCT/US98/27380 Authorized Officer:

Filed: 24 December 1998 F. KRASS

For: AN IRRIGATING MEDIUM FOR ROOT CANALS

DOCUMENTS BEING FILED:

THE PTO STAMP HEREON ACKNOWLEDGES RECEIPT OF:

(1) Transmittal Letter; and
(2) Response to PCT Written Opinion.

NATH & ASSOCIATES
1030 15TH Street, N.W., 6TH Floor
Washington, D.C. 20005
(202)-775-8383

FILE CHECK

Prepared by: JLM

Approved by:

Copy reviewed:

Filed by:

23800.resp.writt.fr

Attorney Docket No. 23800-PCT

IN THE UNITED STATES RECEIVING OFFICE

In re Application of:

RADICAL WATERS (PROPRIETARY) LIMITED et al.

Application No.: PCT/US98/27380 Authorized Officer:

Filed: 24 December 1998 F. KRASS

For: AN IRRIGATING MEDIUM FOR ROOT CANALS

TRANSMITTAL LETTER

Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Sir:

Submitted herewith for filing in the United States Receiving Office is the following:

(1) Transmittal Letter; and
(2) Response to PCT Written Opinion.

Please charge any additional fee that may be required, or credit any overpayment, in connection with this matter to deposit Account No. 14-0112.

Respectfully submitted,

Date: December 13, 1999 By: _____

Gary M. Nath
Registration No. 26,965
Jerald L. Meyer
Registration No. 41,194

NATH & ASSOCIATES
1030 15th Street N.W., 6th Floor
Washington, D.C. 20005
(202) 775-8383
15057.roa2.tl

BOX PCT
ATTORNEY DOCKET 23800-PCT

IN THE UNITED STATES RECEIVING OFFICE

In re Application of:

RADICAL WATERS (PROPRIETARY) LIMITED et al.

Application No.: PCT/US98/27380 Authorized Officer:

Filed: 24 December 1998 F. KRASS

For: AN IRRIGATING MEDIUM FOR ROOT CANALS

RESPONSE TO PCT WRITTEN OPINION

Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Sir:

This is in response to the Written Opinion dated 14 October, 1999, due for reply by 14 December, 1999.

The Authorized Officer is respectfully requested to take the following remarks into account before issuing the International Preliminary Examination Report.

REMARKS

Reasoned Statement under Rule 66.2(a)(ii) that Claim 8 Lacks Novelty Under PCT Article 33(2) and that Claims 1-4, 9 and 10 Lack Inventive Step Under PCT Article 33(3)

The Written Opinion states that claim 8 lacks novelty under PCT Article 33(2) as being anticipated by MEDICAL DISCOVERIES INC., and that claims 1-4, 9 and 10 lack an inventive step under PCT Article 33(3) as being obvious over MEDICAL DISCOVERIES INC. As a basis for this statement, the Authorized Officer contends:

Claim 8 lacks novelty under PCT Article 33(2) as being

anticipated by MEDICAL DISCOVERIES INC.

Claims 1-4, 9 and 10 lack an inventive step under PCT Article 33(3) as being obvious over MEDICAL DISCOVERIES INC. MEDICAL DISCOVERIES INC. teaches the use of electrochemically activated aqueous solutions to treat in vivo infections, and since root canal infections are in vivo infections their treatment would follow logically.

Applicants respectfully traverse this statement.

Applicants respectfully submit that the use of an electro-chemically activated aqueous solution in a root canal treatment is novel. In dental school and the textbooks used therein to teach future dentists, the use of sodium hypochlorite in root canal treatments is universally taught. The textbooks only recommend the use of sodium hypochlorite as the irrigant of choice. Thus, the use of an electro-chemically activated aqueous solution in root canal treatments represents a novel, inventive and radical departure from the standard, accepted, convention and traditional norm.

A further aspect of inventiveness of the use of an electro-chemically activated aqueous solution is the safety of using such an aqueous irrigant. Sodium hypochlorite is an extremely toxic, dangerous, and corrosive chemical compound that has the potential to cause severe tissue damage, necrosis, swelling, pain, infection, and even death. Sodium hypochlorite is also one of the main causes of post-operative pain after root canal treatment. On the other hand, an electro-chemically activated aqueous solution is harmless to living tissue, highly efficient as a microbiocidal agent, and environmentally friendly. Even so, the use of an electro-chemically activated aqueous solution in a root canal treatment has heretofore never been suggested.

Turning now to the MEDICAL DISCOVERIES INC. reference, Applicants would like to point out the following differences between the claimed invention and the reference. The treatment in MEDICAL DISCOVERIES INC. (MDI) reference is

intended for general, systemic, and primarily blood born diseases, and, as such, is intended for intravenous injection into the vascular system of a warm-blooded animal. Conversely, the claimed invention is aimed at a specific, local, intra-pulpal disease and, as such, the electro-chemically activated aqueous solutions are applied strictly to the inside of a tooth, i.e. the pulpal chamber and root canals. There is no suggestion in the MDI reference to use the aqueous solution of the reference directly in a root canal.

The root canal system of the human body is unique for two reasons: it is totally encapsulated by hard tissue; and it has very poor blood supply, and in fact, practically no collateral blood supply. The treatment of the MDI reference is specifically aimed at use in the bloodstream, whereas it is a very definite objective of the claimed root canal invention, not to enter the bloodstream. Accordingly, the diseases against which the treatment of the MDI reference is aimed are very different in nature, etiology and pathogenesis to the diseases of the root canal system, to which the claimed invention is drawn. In particular, the MDI reference does not mention any antibacterial activity of its treatment with its solution. The treatment of the presently claimed invention, though, is primarily aimed at killing all bacteria in root canals and as such, the electro-chemically active agent aqueous solution of the presently claimed invention is primarily an antibacterial solution.

Furthermore, the treatment in the MDI reference is alternatively intended for vaginal, rectal or oral use, or further, for the sterilization of blood or other fluids *in vitro*. The electro-chemically activated aqueous solution of the claimed invention, on the other hand, is used only as a direct disinfectant in the unique environment of the root canal system.

In addition, the treatment of the MDI reference has a

clear and stated purpose of aiding the immune system by producing ozone and super-oxides to aid the body's own defenses in blood tissues. Also, the use of modulating or moderating agents to limit cell damage is very important in the treatment of the MDI reference. However, the use of the electro-chemically active aqueous solution in root canals as claimed in the present invention has a stated objective of killing all of the micro-organisms inside the root canal system. Additionally, the electro-chemically active aqueous solution of the claimed invention does not need any modulating or moderating agents.

Lastly, a difference in the preparation of the respective aqueous solutions exits. The aqueous solution of the MDI reference is prepared by electrolyzing saline solution in one vessel, producing one homogenous solution. Both of the electrodes are housed in the same vessel and as such, there is no separation between the anode and the cathode. In contrast, the treatment of the present invention includes two distinctly separate solutions, a cation-containing solution and an anion-containing solution, with distinctly different characteristics. The solutions are created in two chambers, the anodic chamber and the cathodic chamber, with the respective electrodes being confined to the distinct chambers. By preparing the solutions in the separate chambers, the unique oxidation-reduction potential characteristics of the two electro-chemically activated aqueous solutions are created. In the treatment of the present invention, it is important, but not limiting, to first use the cation-containing aqueous solution followed by using the anion-containing aqueous solution. This treatment is not possible with the homogenous solution as discussed in the MDI reference.

Accordingly, based upon these remarks, Applicants respectfully submit that the use of an electro-chemically activated aqueous solution in the treatment of root canals is

novel and contains an inventive step. There is no suggestion in the MDI reference to use the aqueous solution of the reference in the present invention as claimed.

CONCLUSION

Based upon the above remarks, a favorable Preliminary International Examination Report is respectfully requested.

The Authorized Officer is welcomed to telephone the undersigned attorney if he has any questions or comments.

Respectfully submitted,

NATH & ASSOCIATES

December 13, 1999

Gary M. Nath
Reg. No. 26,965
Jerald L. Meyer
Reg. No. 41,194

NATH & ASSOCIATES
1030 Fifteenth Street, N.W.
6th Floor
Washington, D.C. 20005
(202) 775-8383